

# **Chapter 7**

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## **CONDUCTING AN ENVIRONMENTAL INVESTIGATION**

- 1) What Does the Environmental Investigation Entail?**
- 2) Background to a Hazard Analysis Critical Control Point (HACCP) Risk Assessment**
- 3) Application of HACCP Principles in a Foodborne Illness Investigation**

# CONDUCTING AN ENVIRONMENTAL INVESTIGATION

### Introduction

The local board of health (LBOH) is the public health agency responsible for conducting an environmental investigation in response to a suspect foodborne illness complaint. **The objective of the environmental investigation is to:**

- identify the reason for, or source of contamination, and
- initiate corrective actions, if necessary, to eliminate contaminated foods or poor food handling practices which may result in contaminated foods.

Further illnesses may be avoided if potentially contaminated foods are promptly identified and removed from sale or service to the public, and poor food-handling practices are corrected.

Other reasons for initiating an environmental investigation include government responsibility, consumer expectation, and vindication of innocent establishments. Investigative findings are important information: they are a public record and may be subpoenaed for legal proceedings, as are inspection reports.

## 1) What Does the Environmental Investigation Entail?

The primary objective of the environmental investigation is to determine what specific factors may have contributed to the illness or outbreak and, if discovered, assure that they are corrected. Unlike routine inspections, a quality environmental investigation of a foodborne disease outbreak may take several hours because it involves the evaluation of all suspected processes but starts with a review of the previous routine inspection reports of the implicated food establishment. One must be acquainted with the inspection equipment and forms necessary to conduct a complete investigation. **An environmental investigation should be initiated within 24-48 hours of the receipt of a complaint** and involves the following:

### A. Collecting Food Samples

**To avoid important evidence from being inadvertently discarded during your investigation, always identify and collect leftovers of the suspect food(s) immediately.**

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See Box 4.1 - *Guidelines For Determining Suspect Foods* in Chapter 4-Section 3-A. Food collection should be completed prior to initiating the HACCP risk assessment of the suspect food. Review how to aseptically collect food samples and transport them for analysis. Bring the proper food sample containers and investigation forms with you.

**NOTE:** Guidelines for how to collect food samples are provided in Appendix B. For information on where to obtain food containers, contact the Food Protection Program at 617-983-6712.

### **B. Facilitating Enteric Collections**

As with food samples, stool samples must be collected as soon as possible in order to confirm a clinical diagnosis. Bring an adequate supply of enteric kits and instructions for collection. Determine who is responsible for distributing enteric stool kits to food handlers. Determine who is responsible for instructing food workers on how stool specimens should be collected.

**NOTE:** Further information on obtaining enteric stool kits and instructions on collection can be found in Chapter 6, Section 4. Detailed information on the MDPH Infected Food Worker Policy can be found in Appendix A.

### **C. Inspecting the Food Establishment**

The food inspector or sanitarian should be trained in the provisions outlined in *105 CMR 590.000: Minimum Sanitation Standards for Food Establishments*. Bring the most current version of *105 CMR 590.000*. Bring the necessary equipment to conduct an inspection. An inspector's equipment checklist is provided in Appendix E. A list of food sampling equipment and food submission forms are provided in Appendix B.

### **D. Conducting A HACCP Risk Assessment on Implicated Foods**

Hazard Analysis Critical Control Point (HACCP) is a science-based method of evaluating food handling procedures to identify or prevent hazards which contribute to foodborne disease. Have a food inspector or sanitarian trained in conducting a HACCP Risk Assessment.

**NOTE:** More information on a HACCP risk assessment can be found in Sections 2 and 3 of this chapter. For technical assistance, contact the MDPH Food Protection Program at 617-983-6712.

### **E. Initiating Corrective or Enforcement Actions**

Have a food inspector or sanitarian trained in enforcement (e.g., embargo, voluntary disposal, emergency closure, food worker restrictions) procedures outlined in *105 CMR 590.000*.

Persons conducting the environmental investigation should be knowledgeable in the

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following areas:

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- food microbiology,
- etiology of foodborne disease,
- high-risk factors in foodborne illness outbreaks,
- the application of HACCP principles,
- food preparation review and food establishment investigation procedures,
- regulatory provisions, and
- enforcement procedures outlined in *105 CMR 590.000*.

**Good communication skills** are also required to conduct a thorough investigation. When identifying yourself to the person-in-charge (PIC), explain the purpose of the "foodborne illness" investigation and be prepared for a variety of reactions. Food establishment operators are often tense, nervous, defensive, angry, and, sometimes, in complete denial at the prospect of being responsible for a customer's illness. Stay calm, respectful and professional. Encourage cooperation by explaining the LBOH responsibility, as well as the food establishment's responsibility to ensure that practices and procedures are adequate to prevent foodborne diseases. If necessary, remind the PIC that failure to cooperate in the investigation may result in the suspension or revocation of the food permit. In any situation, maintain an unbiased attitude and assure the PIC that other plausible causes will be addressed.

The designated LBOH spokesperson responsible for talking to the media and affected groups in high-profile investigations (e.g., larger outbreaks) should also be knowledgeable in risk management issues and have a medical or public health background.

**NOTE: If you are uncertain on how to proceed, contact the MDPH Working Group on Foodborne Illness Control (see telephone numbers below).**

### **MDPH Working Group on Foodborne Illness Control**

|   |  |
|---|--|
| Food Protection Program<br>(617) 983-6712                   | For policy and technical assistance with the environmental investigation such as conducting a HACCP risk assessment, initiating enforcement actions and collecting food samples. On-site investigation assistance is often available for larger outbreaks. |
| Division of Epidemiology and Immunization<br>(617) 983-6800 | For technical assistance with the epidemiologic investigation such as obtaining medical histories, coordinating stool specimen submissions and developing questionnaires. On-site investigation assistance is often available for larger outbreaks.        |
| Division of Diagnostic Laboratories<br>(617) 983-6616       | For technical assistance with the collection protocol for food and clinical specimens.   |

### 2) Background to a Hazard Analysis Critical Control Point (HACCP) Risk Assessment

#### A. What is HACCP?

HACCP provides a systematic, science-based approach to food safety. A HACCP-based investigation focuses on the suspect food or meal implicated, rather than on a cursory inspection of the physical and sanitary facilities of the food establishment. The production of the implicated food item is evaluated for hazards which can contribute to the occurrence of foodborne disease. This is done at each step of handling from receipt to sale or service to the consumer.

The ideal steps in conducting a HACCP risk assessment of the implicated food include actual observation of the suspect food being prepared, taking temperatures and identifying potentially faulty food handling practices. Since this may not be feasible if the food establishment is not producing the implicated food or meal at the time of the investigation, it will be necessary to interview the PIC of food production on how the food was handled from receipt to sale or service. General food handling practices should be evaluated by observing food workers and by measuring various potentially hazardous food temperatures.

To effectively conduct a HACCP risk assessment, a sanitarian or food inspector must have a general understanding of applied food microbiology, high-risk factors in food preparation and the application of HACCP principles.

#### B. Applied Food Microbiology

An understanding of how pathogens (disease-causing microorganisms) can contaminate food, survive and/or multiply (and in some cases produce toxins) is essential to evaluate risk. Pathogens may be present in raw foods as well as in infected food workers. Pathogens in food, present either naturally or by contamination, can survive if the food requires no further cooking or is undercooked. It is important to note that while bacteria may survive and multiply in potentially hazardous food, viruses and parasites may survive but cannot multiply without a living host (see Chapter 2, Section 1). Pathogens in infected food workers may be shed in feces, infected lesions and respiratory secretions and thus can be transmitted to food. A list of primary sources of common foodborne pathogens is provided at the end of the chapter (see Attachment 7.1). Use this list when trying to determine the source of contamination.

Potentially hazardous foods (PHFs) are those high-risk foods in which bacteria can survive, multiply and with certain bacteria, produce toxin. Foods with a pH of 4.6 or above and a water activity of 0.85 Aw or greater are regarded as PHFs. PHFs are also defined as any food or ingredient, natural or synthetic, in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms or the slower growth of *Clostridium botulinum*. The pH and Aw for several categories of food are provided at the end of the chapter (see Attachment 7.2).

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### Examples of PHFs include:

- Beef
- Poultry
- Pork
- Finfish
- Shellfish
- Dairy Products
- Eggs
- Vegetables (cooked vegetables, raw bean sprouts, cabbage)
- Starchy Foods (tofu, rice, potatoes, grains)

The optimum growth temperature range for the majority of pathogens is between 60° and 120° F. Some pathogens such as *Listeria* and *Yersinia* grow best under refrigeration temperature ranges. Under optimum growth temperatures, bacteria, in their vegetative state, can double in number every 15-20 minutes. At temperatures below freezing, foodborne pathogens may survive but cannot grow. Most pathogens are destroyed at temperatures above 140° F.

While PHFs may provide the optimum environment for the growth of pathogens, other non-PHF's may be the causal factor in a foodborne illness outbreak by simply acting as the food vehicle in which bacteria, parasites or viruses can survive until ingested. The food listed below, not normally defined as PHFs, have been implicated in foodborne outbreaks.

### Non-PHF's Implicated in Foodborne Illness Outbreaks:

| <u>Food</u>   | <u>Outbreak</u>              |
|---------------|------------------------------|
| Orange juice  | <i>Salmonella</i>            |
| Apple cider   | <i>E. coli</i> O157:H7       |
| Lettuce       | <i>E. coli</i> O157:H7       |
| Raspberries   | <i>Cyclospora</i>            |
| Cantaloupe    | <i>Salmonella</i>            |
| Water/ice     | Viruses                      |
| Mushrooms     | <i>Staphylococcus aureus</i> |
| Garlic in oil | Botulism                     |

Many pathogens which are naturally found in soil-grown vegetables, grains and spices have a dormant **spore** state which can be heat shocked into a vegetative state after cooking. With the exception of infant botulism, bacterial spores do not cause foodborne disease. However, if a pathogen's spore (e.g., *Bacillus cereus* in rice) is heat shocked into its vegetative state after cooking, the *Bacillus cereus* bacteria can then multiply rapidly if left at optimum growth temperatures (60° - 120° F).

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Some pathogens such as *Bacillus cereus* and *Staphylococcus aureus* are **toxin-producing pathogens**. If a food is contaminated and stored at optimum growth temperatures, these organisms can produce heat-stable toxins (i.e., toxins which are not destroyed by heating), which can remain toxic even after reheating (see Chapter 2, Section 1-B).

### C. High-Risk Factors in Food Preparation

Significant factors in foodborne illness outbreaks have been documented in several foodborne disease investigation surveillance studies. Significant factors associated with the occurrence of foodborne disease are listed below and can be divided into three hazard categories: contamination, survival, growth.

#### Contamination:

- *infected person*
- *contaminated ingredients*
- *hand contact/implicated food*
- *unclean equipment*
- *toxic container*
- *cross-contamination*
- *added poisonous chemicals*
- *unapproved source*
- *natural toxicant*
- *consumption of raw or lightly cooked food of animal origin*

#### Survival:

- *inadequate cooking*
- *inadequate reheating*

#### Growth:

- *inadequate refrigeration*
- *preparation several hours before serving*
- *inadequate hot-holding*
- *improper cooling*
- *anaerobic packaging*

Such factors will vary in significance depending on the significant ingredient and how it is prepared. Definitions of these contributing factors and questions you may need to address are outlined below in Section 3-Step 3. Further information on contributing factors associated with the implicated pathogen, significant ingredient and method of preparation can found in Appendix C - HACCP Foodborne Disease Data.

### 3) Application of HACCP Principles in a Foodborne Illness Investigation

Table 7.3 below lists the steps in a HACCP risk assessment. A *HACCP Risk Assessment Form* can be used to facilitate risk assessment of the suspect food and, if used, must be attached to the inspection report. The LBOH can use the *HACCP Risk Assessment Form* to identify the procedures used by the establishment in preparing the suspect food as well as to identify corrective actions initiated as a result of the investigation. **Correction of faulty food handling practices is essential to ensure prevention of further illness.**

**NOTE:** A sample of a blank and completed *HACCP Risk Assessment Form* are provided in Appendix E.

A HACCP risk assessment must be conducted for each suspect food item prepared. If baked chicken and gravy is the suspect food, one should evaluate separately how each was prepared. In outbreaks, when multiple foods have been identified, a *HACCP Risk Assessment Form* can be used to evaluate procedures for a particular category of food such as soups, salads, or sandwiches.

**TABLE 7.3 STEPS IN A HACCP RISK ASSESSMENT**

1. Identify ingredients, weight/volume, and steps involved in the preparation of suspect food(s).
2. Identify food-handling procedures at each step in the preparation of suspect food(s).
3. Based on observation or interview, identify potential hazards and critical control points (CCP).
4. Identify violations and initiate corrective actions.
5. Verify corrective actions undertaken by the food establishment.

#### **STEP 1. Identify ingredients, weight/volume, and steps involved in the preparation of suspect food(s).**

##### **Ingredients in the suspect food.**

Obtain recipes for all suspect food items. List all ingredients for each suspect food item. Ingredients must be from an approved source, especially high-risk ingredients such as raw shellfish or canned low-acid foods. It is usually not necessary to obtain exact measurements of each ingredient unless there is a question on the pH of the food. Note new changes in recipes or ingredient substitutions. **NOTE:** Recipes are proprietary information and must be treated with strict confidentiality.

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### **The suspect food is contaminated at the source (farm/ocean) or at the manufacturing level.**

Contaminated produce, eggs, seafood and commercially-processed foods have been implicated in many foodborne illness outbreaks. When such products, contaminated at the source, are implicated, it is crucial to obtain as much information as possible from the food establishment or consumer to identify the exact source and/or manufacturer/distributor. Product lot numbers, expiration dates and sales records are necessary when conducting a trace back to identify an implicated source. When investigating such products, be sure to obtain the following product information.

#### **Manufactured Product Identification**

- |                                  |   |
|----------------------------------|---|
| - Brand Name                     | - Package Type                              |
| - Product Name                   | - Date of Purchase                          |
| - Code/Lot Number                | - Manufacturer Name and Address             |
| - Expiration/Sell by/Use by Date | - Distributor Name and Address              |
| - Size/Weight                    | - Retail Food Establishment Where Purchased |

Shellfish identification tags should always be obtained for clams, oysters, quahogs and other molluscan shellfish associated with a foodborne illness. For information on conducting food tracebacks, see traceback article (Attachment 7.4) at the end of this chapter.

### **Volume of the suspect food prepared by the food establishment.**

List the weight/volume of the suspect food prepared. Large volumes may indicate problems with cooling or food handling procedures, especially if the food was prepared a day or more before service. If the volume was greater than what is normally prepared, different procedures may have been used.

### **Suspect food preparation schedule.**

Dates and the length of time are important information needed to determine potential time/temperature abuse. It is important to document **date and time prepared**, when applicable, to determine if there was ample time for temperature abuse which may have resulted in the growth of pathogens or the production of toxin.

### **Identify steps in preparing the suspect food.**

Each step (e.g., store, thaw, cook, cool, serve) in the preparation of a food item is regarded as a "**control point**." (More information on control points can be found in next step, Step 3. List each step or control point on the *HACCP Risk Assessment Form*. Listing the steps as a flow chart permits the visualization of each preparation step.

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### **STEP 2. Identify food handling procedures at each step in the preparation of suspect food(s).**

Clearly document **how the food was handled** at each step. The method used to identify food handling procedures at each step is to observe the actual process. Since this may not be feasible in some situations, it is essential to interview the manager-in-charge of food production and then walk-through the preparation steps in the kitchen afterwards. Identify how suspect foods were thawed, cooked, cooled, reheated, served and transported. Identify how food workers determined final cooking temperatures. Indicated what equipment was used in the preparation of the suspect food. Specify if food workers use disposable gloves or utensils to handle cooked and read-to-eat foods. Indicate handwashing practices observed.

Clearly document **who prepared the food**. It is recommended that the initials of the **employee responsible for handling food** be documented. An infected food worker with poor hygiene may be the source of contamination. The initials (versus “line cook” or “waitress”) are helpful when comparing the positive or symptomatic food workers to their job functions to determine if there is a relationship. Inquire if the food worker had been recently ill. Ask if the worker is a new employee or new to the particular operation because a new or different food worker unaware of the proper procedure may have been responsible for preparing the suspect food. Review the food establishment's sick or infected food worker policies. See Appendix A for the MDPH Infected Food Handler Policy.

**Focus on the significant factors in foodborne illness outbreaks.** When conducting a HACCP Risk Assessment, focus on poor food handling practices which can contribute to foodborne disease. Definitions for each significant factor are listed in Step 3 in addition to questions that may need to be addressed during your assessment.

### **STEP 3. Based on observation or interview, identify potential hazards and critical control points (CCP).**

The level of risk for a suspect food depends on the probability of occurrence of a hazard or the sequential occurrences of several hazards identified in the preparation procedure.

As mentioned earlier in this chapter, the three main microbiological hazards are:

- a) Contamination (C)**
- b) Survival (S)**
- c) Growth/Toxin Production (G/T)**

#### **a) Contamination.**

Determine if there are risks at each step in the food preparation for microbial CONTAMINATION (C) from either the food worker, food, or improperly cleaned and sanitized equipment /utensils. (Food could be raw animal foods already contaminated or foods

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which were contaminated at the point of harvesting and intended to be consumed raw such as lettuce, raspberries and unpasteurized apple cider.)

Epidemiological data indicates that microbiological hazards pose the highest risks to the greatest number of persons. Physical and chemical hazards usually affect individuals rather than groups. Microbiological contamination such as bacteria, viruses and parasites are present in infected food workers and raw foods of animal origin. Indirect or cross-contamination from raw foods of animal origin to ready-to-eat foods that will receive no further heating can also result in microbiological contamination.

### **Contributing Factors Associated With Contamination:**

***Contaminated Ingredients:*** The suspect food or a component of the food contained the pathogenic agent when it arrived at the point of preparation.

- Determine if the suspect food harbors contaminants normally found in soil, fertilizers or raw animal foods (e.g., raw meat, poultry, seafood, root vegetables etc.).
- Check to determine if the water/ice supply was possibly contaminated.
- Check to determine if back-flow prevention devices were present on plumbing cross-connections.
- Check to determine if the suspect food was from an approved source.
- Check to determine if the source may have contributed to the suspect foods contamination (e.g., shellfish from a contaminated growing bed).

***Unapproved Source:*** The suspect food was obtained from a source that does not comply with appropriate regulatory standards (e.g., shellfish harvested from closed growing beds).

- Determine if all foods (including water/ice) were obtained from an approved source.
- Check identification tags on shellfish and if they are retained for 90 days.

***Infected Person:*** A food worker involved in the preparation of the suspect food was infected or was suspected as being infected at the time the food was prepared. This individual was identified as the probable source of the agent in the outbreak.

- Identify the persons responsible for preparing the suspect foods.
- Determine if any of the food workers were ill before or during the time that the suspect food was being prepared.
- Check if any of the food workers were observed with infected cuts or wounds on their fingers or hands.

***Consumption of Raw or Lightly Cooked Food of Animal Origin:*** The suspect food was eaten raw or after a heat treatment that would not have reduced the level of agent contamination to below an infectious dose.

- Determine if the suspect food of animal origin was served raw or undercooked?
- If required by law, check if consumer advisories were properly posted?

***Cross-Contamination:*** The pathogen was transferred to the suspect food during preparation by contact with contaminated worker hands, equipment, utensils, drippage, or spillage. If

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worker hands were the mode of contamination, the worker was not necessarily infected with or a carrier of the organism.

- Determine if raw foods were stored separately from cooked and ready-to-eat foods.
- Check if food workers were properly washing their hands and using a physical safety barrier such as disposable gloves, deli papers and utensils in-between handling raw and cooked or ready-to-eat foods.
- Check equipment, utensils and food contact surfaces for proper cleaning and sanitizing between use

***Unclean Equipment:*** The suspect food was prepared with or stored in equipment that was contaminated with the agent.

- Check if the equipment and utensils used to prepare the suspect food were properly cleaned and sanitized in accordance with *105 CMR 590.000*.

***Hand Contact with Implicated Food:*** A food worker who was identified as the source of the agent prepared the vehicle with his/her bare hands.

- Check if infected workers used their bare hands to handle or to prepare cooked and ready-to-eat foods.
- Determine if food workers are trained to use physical safety barriers such as disposable gloves, deli papers and utensils in-between handling raw and cooked or ready-to-eat foods.

***Added Poisonous Chemicals:*** The chemical agent was deliberately or inadvertently added to the suspect food. In former cases, this addition typically occurred at the time of preparation or packaging of the vehicle.

- Determine if any toxic substances were improperly stored or used around the suspect food.
- Check if there were any recent situation involving a disgruntled employee possibly seeking revenge.
- Investigate where any toxic substance in the immediate vicinity of the suspect food may have been mislabeled.

***Natural Toxicant:*** A chemical agent of biologic origin that occurs naturally in the suspect food or bioaccumulates in the suspect food prior to or soon after harvest.

- Investigate whether a suspect food is known to harbor natural toxicants (e.g., histamine in scombroid fish, aflatoxins in grain, toxins in poisonous mushrooms, dinoflagellate toxins in shellfish).

***Toxic Container:*** A chemical agent originated in the material from which the food container was made. The agent migrated from the container into the suspect food.

- Determine if the suspect food was in direct contact with lead, copper, aluminum, tin, cadmium or other heavy metals.
- Is the suspect food acidic (pH < 7)? The more acidic the product, the greater potential for metals to leach into foods. Check to see that food is stored in the proper containers.

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### b) Survival.

Determine if pathogens SURVIVED (S) the cooking process. The survival of pathogens is determined by the "thermalization" or cooking procedure used. Pathogens are easily destroyed by adequate cooking or reheating. The consumption of undercooked or raw foods of animal origin is a significant factor in foodborne disease outbreaks. Massachusetts is currently in the process of adopting time/temperature cooking and reheating requirements outlined in the 1997 Food Code. Time/temperature cooking requirements are listed below:

#### Time/Temperature Cooking Requirements

| Temp.  | Holding Time   | Food Product  |
|--|--|---|
| 145° F   | 15 seconds   | Fish/meat/game animals/raw shell eggs that are broken and prepared for immediate service.   |
| 145° F<br>150° F<br>155° F   | 3 minutes, or<br>1 minute, or<br>15 seconds  | Pork/ratites*/injected meats/comminuted* fish, meat and game animals/raw shell eggs that are broken and held prior to cooking or are held prior to service after cooking. |
| 165° F   | 15 seconds   | Poultry/wild game animals as allowed by law/stuffed fish, meat, pasta poultry, ratites or stuffing containing fish, meat, poultry or ratites.                             |
| 130° F<br>132° F<br>134° F<br>136° F<br>138° F<br>140° F<br>142° F<br>144° F<br>145° F | 121 minutes<br>77 minutes<br>47 minutes<br>32 minutes<br>19 minutes<br>12 minutes<br>8 minutes<br>5 minutes<br>3 minutes | Whole beef roasts. (Refer to <i>105 CMR 590.000</i> for appropriate oven temperature based on roast weight. Holding time may include post-oven heat rise.)                |

\* Ratites = ostrich and emus.

\* Comminuted. Reduced in size by methods including chopping, flaking, grinding or mincing.

#### Contributing Factors Associated With Survival:

**Inadequate Cooking:** The suspect food was not heated to a temperature and for a time adequate to destroy the agent or to reduce the level of contamination to below an infectious dose.

- Were the raw animal origin foods cooked to proper time/temperatures in accordance with *105 CMR 590.000*?
- Check if the establishment has a food stem thermometer and whether it is used to test

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final cooking temperatures.

- If required, are cooking temperature logs maintained?

***Inadequate Reheating:*** The suspect food, which had been previously cooked and cooled, was not heated to a temperature sufficient to destroy the agent or to reduce the level of contamination to below an infectious dose.

- Determine how the suspect food was reheated.
- Check to determine if the suspect food was properly reheated in accordance with *105 CMR 590.000*.
- Determine if a thermometer was used to test the final reheat temperature of the suspect food.

### **c) Growth/Toxin Production.**

Determine if the pathogens had ample time to GROW (G) AND/OR PRODUCE TOXIN (T). The growth of pathogens and the production of toxins can occur in PHFs which achieve temperatures between 45° and 140° F for several hours. Time/temperature abuse can result from inadequate cooling procedures, holding at room temperature and inadequate hot and cold holding units. While reheating contaminated food may destroy pathogens, it may not deactivate heat-stable toxins produced by pathogens such as *Staphylococcus aureus*. It is recommended that potentially hazardous foods be cooled from 140° F to 70° F within two hours and then to 41° F (or 45° F) or less within four hours.

### **Contributing Factors Associated With Growth and Production of Toxins:.**

***Improper Cooling:*** The suspect food was cooled from a cooking or ambient air temperature to a refrigeration temperature by a means that allowed the growth of a pathogen to an infectious dose or the production of toxin.

- Determine if implicated PHFs were cooled to 45° F within 4 hours by pre-chilling ingredients, using shallow containers, ice baths or reducing the size of the product.

***Inadequate Refrigeration:*** The suspect food was not held at a temperature of 45° F or less either due to improperly functioning refrigeration equipment or because it was being held outside of refrigeration. The period of time held at an improper temperature was sufficient to permit the growth of a pathogen to an infectious dose or the production of toxin.

- Determine if there was an adequate number of refrigeration units to maintain the suspect PHF at or below 45° F.
- Determine if refrigeration units were properly operating at or below 45° F.

***Inadequate Hot Holding:*** The suspect food (PHF) was not held at or above 140° F due to improperly functioning hot holding equipment or was not being held in hot holding equipment. The period of time the food was held was sufficient to permit the multiplication and growth of the pathogen to an infectious dose.

- Determine if the suspect food was left out for storage or display at ambient air temperature.

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- Determine how long the suspect food (PHF) was below 140° F.
- Determine if temperatures of suspect foods in hot holding units were at or above 140° F.
- Determine if the food workers have and use thermometers to measure temperatures of the suspect PHFs in hot holding units.
- If required, check temperature logs for hot holding units.

***Preparation Several Hours Before Service:*** The suspect food was prepared long before service, and this practice permitted a time/temperature abuse of the food.

- Determine the length of time between preparation and service of the suspect food.
- Determine how long the suspect food was stored between preparation and service.

***Anaerobic Packaging:*** The suspect food was stored in a container that provided an anaerobic environment. This environment permitted the multiplication and growth of the agent.

- Check to determine whether the suspect food was stored in an anaerobic package or container (e.g., vacuum packaging, container filled to capacity and tightly covered, hermetically sealed containers and garlic in oil products).
- If the suspect food was in a vacuum package or container, investigate at what temperature it was stored.
- Determine if the suspect food was prepared in a cook-chill or sous-vide operation.
- If the suspect food was in a vacuum package or container, review the label storage instructions.

### **Critical control points.**

A **critical control point (CCP)** is a preparation step in which a hazard, if present, can result in a foodborne disease. For example, any step in the production of a ready-to-eat food (e.g., tuna salad), where contamination is likely to occur, may be considered a CCP since pathogens introduced during storage or preparation may survive until ingested. Thus, each step where contamination occurs in a ready-to-eat food is “critical.” However, if a food worker handles raw chicken with bare hands, this step would not be critical, since the chicken would be cooked in the next step destroying all pathogens introduced into the food. In this procedure, cooking would be a “critical control point” because adequate cooking is necessary to destroy all pathogens naturally present or introduced during preparation. Failure to cook the chicken properly would allow the survival of pathogens, which could result in a foodborne illness.

### **STEP 4. Identify violations and initiate corrective actions.**

**Document Violations.** This step in the investigation is critical especially if further enforcement action is necessary. Violations may be referenced on the *HACCP Risk Assessment Form* in the “Item No.” column and then attach the *HACCP Risk Assessment Form* to the food establishment inspection report form. If a *HACCP Risk Assessment Form* is not completed at the time of the investigation, the violations must be documented on the

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narrative section of the inspection report form. Failure to properly document violations may result in the LBOH being legally challenged for actions.

**Document Corrective Actions.** Indicate immediate corrective or enforcement actions taken as well as how and when existing violations will be corrected, particularly for critical control points. If violations involving critical control points are detected, a **reinspection** should be conducted within 24 - 48 hours to verify correction. In the column *Verified* on the *HAACP Risk Assessment Form* indicate the date and the inspector verifying correction. Corrective actions may include:

- *Modifying faulty food handling practices*

Initiating corrective actions is the most critical aspect of the environmental investigation if unsafe food handling practices are discovered. Ensuring that faulty food handling practices, which can result in foodborne disease, are corrected, is one of the primary objectives of the investigation. **Emphasize critical control points correction.** Discuss with the food manager monitoring procedures that can be implemented by the food establishment to ensure that steps designated as *critical* are properly carried out by employees.

Correction plans can include recommendations to improve food safety. For example, the use of raw eggs in a Caesar salad dressing is not in violation of the regulations. However, recommending that the establishment use a pasteurized product is reasonable since the use of a pasteurized product can reduce the risk of disease transmission.

- *Education*

Efforts to educate the operator on the risks posed by identified poor food handling practices should be made by the sanitarian. In some situations, it may be necessary for the operator to hire a consultant to assist in making changes or training their staff. Food operators may also be required to participate in a food safety management program if not already certified in food safety.

- *Removal of contaminated food from sale or distribution*

If it is determined that food prepared on the premises is possibly contaminated and may cause a foodborne illness, the LBOH may initiate the voluntary disposal of the food or an embargo until the food can be tested in a laboratory. Such action should be taken only with clear evidence of contamination or time/temperature abuse.

Most of the focus should be placed on foods that will not receive further cooking or reheating, since it is these foods in which bacteria and toxins, if present, may survive until ingested. However, some food poisonings, such as scombroid poisonings can occur even after food is cooked. Remember that corrective actions may not always require disposal. Corrective actions suggested for time/temperature abuse situations during cold holding, hot holding, cooling, cooking, and reheating can be found in an attachment entitled *PHF Temperatures* in Appendix E.

When there is strong evidence that contaminated food has been distributed by the establishment, it may be necessary to issue a press release warning consumers not to eat the

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food. (An example of a hepatitis A press release can be found in Appendix E.) A food recall may also be initiated by the implicated food manufacturer, distributor or by federal and state food regulatory agencies.

- *Restriction of infected food workers*

If a sick food handler is noted at any time during the environmental investigation, take steps to restrict the food handler from working with food in accordance with *105 CMR 590.000: Procedures When Infection is Suspected*. Detailed procedures for restricting infected food handlers are outlined in Appendix A.

- *Emergency closure or suspension of operations*

In certain situations, it may be necessary to close an establishment or suspend a particular operation if imminent health hazards exist that cannot be corrected immediately. Failure to immediately correct violations that may result in a foodborne disease (normally associated with critical control points) should invoke an emergency closure or suspension of operation(s).

For example, if it is discovered that a mechanical salad bar refrigeration unit is not maintaining PHF temperatures at or below 45°F, and there is no ice source, the salad bar operation should be closed until the unit is repaired. Another example that may warrant an emergency closure is in an outbreak situation when it is determined that the majority of the food workers must be restricted from working with food, and there are no replacement workers. A food establishment may desire to voluntarily close to avoid negative publicity. Remember, closures and suspensions are a serious matter to all involved and should be well planned before implemented.

If a closure or suspension is initiated, the permit holder and the person-in-charge must be notified of the order in writing. The order is effective upon posting on the premises.

Afterwards, the board of health must hold a hearing within three business days after receipt of a written request for hearing. Whether or not a hearing is requested, the board of health may end the suspension at any time if the reasons for the suspension no longer exist.

### **Elements of an Emergency Closure Order**

An emergency closure order must state the following:

- The board of health has determined that an imminent health hazard exists which requires immediate suspension of operations or closure,
- The violations leading to that determination, and
- A hearing will be held if a written request is filed with the board of health by the permit holder within 10 days of receipt of the notice of suspension.

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### **STEP 5. Verify corrective actions undertaken by the establishment.**

All corrective actions must be verified by the LBOH to ensure that steps to reduce or eliminate the hazards have actually occurred. Failure to correct critical violations or to comply with other necessary measures (e.g., food worker specimen submission or work restrictions) should result in the LBOH taking further enforcement actions such as suspension or emergency closure. Verification may be completed during the investigation by actually observing the corrective actions or by reinspection.

## **Conclusion**

A HACCP risk assessment may require more than one contact with the food operator during site visits or telephone calls in order to obtain all the information necessary to assess the procedures. Elements in the investigation may change and can require shifts of focus in suspect procedures. Try to stay open-minded and patient. When investigating suspect foods which may have been contaminated prior to being received at the retail food establishment, it is important to obtain as much product information as possible to identify the exact source, and remove contaminated products from distribution.

Conducting a HACCP risk assessment of the implicated food is necessary in order to effectively identify potential hazards or points of contamination and time/temperature abuse. A report that reflects a HACCP-based investigation provides specific information to the reviewer (food establishment operator, complainant, board of health members, MDPH Working Group on Foodborne Illness Control, lawyers, etc.) on how the food was handled by the establishment.

Findings may demonstrate how a food establishment is employing safe food handling procedures in preparing the suspect food. Findings may also reveal critical control points in the preparation of the suspect food that were not being safely performed or monitored. In this case, a HACCP risk assessment will clearly identify faulty food handling practices as well as the recommendations to initiate corrective actions. Poor food handling practices can be replaced with safe practices and procedures, thereby averting future occurrences of foodborne disease.

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### ATTACHMENT 7.1

#### Primary Sources of Common Foodborne Pathogens

##### Human beings:

*Salmonella typhi* - intestinal tract, feces, urine  
*nontyphi Salmonella* - intestinal tract, feces  
*Shigella* - intestinal tract, feces  
*Escherichia coli* (enteroinvasive, enterotoxigenic, enteropathogenic strains) - intestinal tract (*E. coli* normal flora), feces  
*Staphylococcus aureus* - nasal passages (normal flora), skin (normal flora), lesions containing pus  
*Streptococcus pyogenes* - skin and throat infections  
*Clostridium perfringens* - intestinal tract (normal flora), feces  
Norwalk-like viruses - feces and respiratory tract  
Hepatitis A virus - feces  
*Giardia lamblia* - intestinal tract, feces  
*Pseudomonas aeruginosa* - skin

##### Fowl and mammals (meat and poultry products):

*nontyphi Salmonella* - intestinal tract, feces, skin/feather contamination  
*Campylobacter jejuni/coli* - intestinal tract (normal flora), feces, skin/feather contamination  
*Escherichia coli* (Enterohemolytic strains) - intestinal tract (*E. coli* normal flora), feces  
*Clostridium perfringens* - intestinal tract, (normal flora), feces  
*Yersinia enterocolitica* - intestinal tract, feces, tongues of swine  
*Staphylococcus aureus* - cows udder and teat canal, feathers, bruised tissue of fowl, nasal passages (normal flora), skin (normal flora), hair, lesions containing pus

##### Raw milk:

*nontyphi Salmonella* - intestinal tract, feces, skin/hair contamination, hands of milker  
*Campylobacter jejuni/coli* - intestinal tract (normal flora), skin/hair contamination  
*Escherichia coli* - intestinal tract (*E. coli* normal flora), feces  
*Clostridium perfringens* - intestinal tract (normal flora), feces  
*Yersinia enterocolitica* - intestinal tract, feces  
*Staphylococcus aureus* - cows udder and teat canal, nasal passages (normal flora), skin (normal flora), hair, lesions containing pus, hands of milker  
*Brucella* spp. - systemic infection, milk  
*Mycobacterium bovis* - systemic infection, milk  
*Coxiella burnetii* - infection, milk

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### **Finfish, shellfish, marine crustacea:**

*Vibrio parahaemolyticus* - sea water natural habitat, fish surfaces, shellfish  
*Vibrio cholerae* non-O1 - sea water natural habitat, fish surfaces, shellfish  
*Vibrio cholerae* O1 - sewage pollution of water habitat, fish surfaces, shellfish  
*Vibrio vulnificus* - sea water natural habitat, shellfish, fish surfaces  
Norwalk-like viruses - sewage pollution of water habitat  
Hepatitis A virus - sewage pollution of water habitat  
Paralytic shellfish poison - toxic marine plankton  
Ciguatoxin - toxic marine plankton and certain fish in region  
Scombroid toxin - finfish containing high levels of histidine and improper cooling of fish after catching that allows growth of certain bacteria that break down histidine to histamine compounds

### **Soil and soil-grown vegetables, cereals, spices:**

*Listeria monocytogenes* - soil natural habitat, moisture on floors  
*Clostridium botulinum* - soil natural habitat  
*Clostridium perfringens* - soil natural habitat, and fecal droppings  
*Bacillus cereus* - soil natural habitat  
All enteric pathogens listed above if right soil or sewage fertilization

### **Water:**

*Aeromonas hydrophila*  
*Pseudomonas aeruginosa*  
*Yersinia enterocolitica* - stream water contaminated by animals  
*Giardia lamblia*  
All enteric pathogens listed above if sewage pollution occurs

Source: Used with permission from Frank Bryan, Ph.D., MPH, Food Safety Consultation and Training, 8233 Pleasant Hill Road, Lithonia, GA 30058, (770-760-1569), 1996.

### ATTACHMENT 7.2

#### Effects of pH

The pH of a food can be used to either encourage or discourage the growth of microorganisms. In general, bacteria multiply most rapidly when the pH is near neutrality. Few pathogenic foodborne organisms can grow at a pH as low as 4.5 and none, except the toxigenic fungi, when the pH drops below 4.0. The pH of a food has a strong bearing on the time/temperature equation necessary to destroy foodborne pathogens. In general, for any given temperature, the lower the pH of the food product, the more rapidly the pathogens will be killed.

| pH of Selected Foods                                     |     |
|--|-----|
| Food   | pH  |
| Limes  | 2.0 |
| Lemons   | 2.2 |
| Vinegar, plums   | 2.9 |
| Prunes, apples, grapefruit (3.0-3.3)                     | 3.1 |
| Rhubarb, dill pickles                                    | 3.2 |
| Strawberries, lowest acidity for jelly                   | 3.4 |
| Peaches  | 3.5 |
| Raspberries, sauerkraut                                  | 3.6 |
| Sweet cherries   | 3.8 |
| Pears  | 3.9 |
| Acid fondant, acidophilus milk                           | 4.0 |
| Tomatoes (4.0-4.6)                                       | 4.2 |
| Lowest acidity for processing at 1000                    | 4.4 |
| Buttermilk   | 4.5 |
| Bananas, egg albumin, figs, isoelectric point for casein | 4.6 |
| Pumpkins, carrots  | 5.0 |
| Turnips, cabbage, squash                                 | 5.2 |
| Sweet potatoes, bread                                    | 5.4 |
| Asparagus, cauliflower                                   | 5.6 |
| Meat, ripened  | 5.8 |
| Tuna   | 6.0 |
| Potatoes   | 6.1 |
| Corn, oysters, dates                                     | 6.3 |
| Egg yolk   | 6.4 |
| Milk (6.5-6.7)   | 6.6 |
| Shrimp   | 6.9 |
| Meat, unripened  | 7.0 |
| Egg white  | 8.0 |

Source: George, Harvey. *Inspecting The Food Service Establishment: Microbiological Considerations*, MDPH, *Food and Drug Reporter*, July 1987, Vol. 5, Issue 87-3.

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### Effects of Water

Effective growth of microorganisms in food products requires the presence of a minimum water content. This minimal water content or water availability is referred to as the *water activity* of the food or  $A_w$ . The maximum theoretical value for  $A_w$  is 1.0, which is that of pure water. As a solution becomes more concentrated or a food becomes more dry, its vapor pressure decreases and hence its  $A_w$  decreases. Most foodborne pathogens have a very narrow  $A_w$  range, with rapid growth taking place in a  $A_w$  range from 0.98 to 0.999, and growth ceasing when the  $A_w$  drops below 0.94 to 0.96. Many organisms have the ability to remain viable for long periods in dried foods with a low  $A_w$ , but die rapidly in heavily salted foods that have a low  $A_w$ . The  $A_w$  of a food is an integral factor in the time-temperature sterilization equation required to kill foodborne pathogens; for example, at any given lethal temperature, the lower the  $A_w$ , the longer the exposure time required for killing.

#### Approximate $A_w$ values of Selected Foods

| <b><math>A_w</math></b> | <b>Foods</b>   |
|-------------------------|--|
| 1.00 - 0.95             | Fresh meat, fruit, vegetables, canned fruit in syrup, canned vegetables in brine, frankfurters, liver sausage, margarine, butter, low-salt bacon |
| 0.95 - 0.90             | Processed cheese, bakery goods, high-moisture prunes, raw ham, dry sausage, high-salt bacon, orange juice concentrate                            |
| 0.90 - 0.80             | Aged cheddar cheese, sweetened condensed milk, Hungarian salami, jams, candied peel  |
| 0.80 - 0.70             | Molasses, soft dried figs, heavily salted fish   |
| 0.70 - 0.60             | Parmesan cheese, dried fruit, corn syrup, licorice   |
| 0.60 - 0.50             | Chocolate, confectionery, honey, noodles   |
| 0.40                    | Dried egg, cocoa   |
| 0.30                    | Dried potato flakes, potato crisps, crackers, cake mixes, pecan halves   |
| 0.20                    | Dried milk, dried vegetables, chopped walnuts  |

Source: George, Harvey. Inspecting The Food Service Establishment: Microbiological Considerations. *MDPH, Food and Drug Reporter*. July 1987, Vol. 5, Issue 87-3.

### ATTACHMENT 7.4

#### **Traceback Methodology - *Cyclospora Cayetanensis* Outbreak Example**

Traceback information is essential in many foodborne illness outbreaks. Tracebacks are necessary to identify possible sources of contamination and to quickly identify and correct an undesirable situation. Many individual case reports of foodborne illness have been linked to a common source of contamination through the process of a traceback investigation. Specific codes assigned to a particular food product as well as specific invoice information relative to each and every distributor should be included in the tracing back of a particular food item. Every step of a traceback investigation needs to be properly identified and properly documented. A conventional traceback usually begins with the information available at the time of purchase of a specific food item by a consumer and extends back to the very beginning of its production. Traceback has been especially beneficial in those outbreaks that have been the result of contamination caused by both *Salmonella* and *E. coli* O157:H7.

The outbreak of cyclospora infection that occurred this past summer (1997) in Massachusetts was associated with similar outbreaks occurring in fourteen other states and Canada. Multiple epidemiologic analyses strongly implied that the consumption of contaminated fruit, specifically raspberries, was responsible for causing illness. Onset times and symptomatology of illness was similar in most reported cases. Traceback information was used to help identify the source and site of product contamination. Information relevant to each and every step was considered in the process of tracing back this specific food item. All of the steps from harvesting to consumption were considered in the traceback of the implicated fruit. The Centers for Disease Control and Prevention (CDC) coordinated the traceback investigation of all the states associated with this outbreak and provided a database that was useful in tabulating and summarizing pertinent information relative to the investigation.

Local health departments may also be asked for participation in tracebacks. They will generally work in conjunction with the State Health Department in obtaining information relevant to the origin of a specific food product.

Tracing back a product to its point of origin requires obtaining certain basic and essential information which should include the following:

- Code numbers
- Lot numbers
- Sell by dates
- Expiration dates
- Wholesalers
- Distributors
- Dates received

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The complete product name as well as the identity and the location of each distributor needs to be included in the traceback. The size of a package or container and type of packaging should be recorded. Invoices from each distributor should be provided. Invoice information should include the identity of a product as well as the exact origin of the product. The quantity of product purchased and the date of purchase should also be included as relevant information. Traceback should start with the purchase of the product by the consumer. The validity of a traceback is strongly dependent upon proper documentation. Receipts and labels are essential in a meaningful traceback. If a label or statement of purchase is not available, then every attempt should be made to seek accurate information relative to date and location of the purchase of the food item in question. Traceback should include all of the locations that a particular product was purchased by the consumer. For example, in many cases, raspberries were purchased from several different locations by the same consumer for the same event. All of these establishments were in fact included in the traceback of raspberries.

Surveillance data indicated that the illness caused by the protozoal parasite *Cyclospora cayetanensis* was due to the ingestion of contaminated raspberries. Traceback information indicated that the contaminated raspberries originated in Guatemala. The Massachusetts traceback investigation also implicated Guatemalan raspberries. Several different distributors were involved with the handling of raspberries. Most of the distributors were housed in one central location. Since the shelf life of this fruit was approximately five days, the time of distribution was rather limited. Invoices from all distributors were collected and examined.

Traceback data indicated that Guatemala was responsible for producing the contaminated raspberries. A cooperative system of farming and the intermingling of produce at one point of collection in Guatemala has made the identification of the exact source and site of contamination difficult. Even though contaminated raspberries from Guatemala have been strongly implicated as the reason for illness occurring, product testing as well as environmental sample testing has not identified the exact cause of contamination. Traceback investigation was in fact very helpful in identifying Guatemala as the source of contaminated raspberries and did rule out the possibility of other countries providing contaminated fruit.

Source: Leonard J. Letendre D.V.M., M.S., R.S., Massachusetts Department of Public Health, Food Protection Program. 1997.